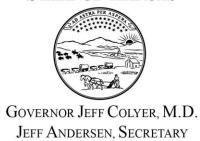
STATE OF KANSAS

DEPARTMENT OF HEALTH AND ENVIRONMENT DIVISION OF HEALTH CARE FINANCE LANDON STATE OFFICE BUILDING 900 SW JACKSON, SUITE 900 N TOPEKA, KS 66612-1220



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Drug Utilization Review Board Meeting Agenda, Open Session April 11, 2018 10:00 a.m. – 2:00 p.m.

Meeting Location

DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619

Board Members

Moneeshindra Mittal, MD James Backes, PharmD Tim Heston, DO John Kollhoff, PharmD Roger Unruh, MD LaTonyua Rice, PharmD, CGP

KDHE-DHCF Staff

Annette Grant, RPh Carol Arace, Administrative Assistant Roxanne Chadwell, PharmD, CSP Dr. Greg Lakin, Chief Medical Officer

DXC Technology/HID Staff

Ellen McCaffrey, BSN, MSN
Taylor DeRuiter, PharmD

Karen Kluczykowski, RPh Kathy Kaesewurm, RN, BSN

MCO Staff

Angie Zhou, PharmD, **Sunflower State Health Plan**Jennifer Murff, RPh, **UnitedHealthcare Community Plan**Lisa Todd, RPh, **Amerigroup**

- I. CALL TO ORDER
 - A. Announcements
- II. OLD BUSINESS
 - A. Review and Approval of October 11, 2017 Meeting Minutes
 - B. Review and Approval of January 10, 2018 Meeting Minutes
- III. NEW BUSINESS
 - A. Miscellaneous Items
 - 1. Fee-for-Service Retrospective Drug Utilization Review Topic Selections

The DUR Board will select topics for the two (2) RDUR intervention topics between April and August 2018.

- i. Topic Presentations
- ii. Board Discussion

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2. Fee-for-Service Retrospective Drug Utilization Review Outcomes Report

The report from the 2017 Medicaid fee-for-service Drug Utilization Review interventions will be presented to show outcomes from the intervention program.

- i. Presentation
- ii. Board Discussion

B. New Preferred Drug List (PDL) Class

1. ADHD – Miscellaneous Type

At the March 2018 PDL meeting, the committee approved the addition of miscellaneous ADHD agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

C. Revised Prior Authorization (PA) Criteria

1. Anti-Constipation Agents (Trulance® [plecanatide])

Trulance is a guanylate cyclase-C (GC-C) agonist indicated for the treatment of chronic idiopathic constipation in adults and is included in the Anti-Constipation Agents PA Criteria. The prior authorization criteria was last revised in April 2017. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. **Botulinum Toxins**

Botulinum toxins carry multiple FDA-approved indications for use. Prior authorization criteria were last revised in October 2016. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

3. **CFTR Modulators**

Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are indicated for the treatment of cystic fibrosis (CF). Prior authorization criteria was initially approved in July 2017. Since that time, Symdeko has been FDA-approved for the treatment of patients 12 years of age or older. The prior authorization criteria are being revised to include the new agent to ensure appropriate and cost-effective use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Somatropin Products

Somatropin products are used for several indications in both children and adults. Prior authorization criteria were last revised in July 2017. Since then, Norditropin has been FDA-approved for the treatment of Prader-Willi Syndrome and Zomacton has been FDA approved for growth hormone deficiency in adults. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

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5. Humira® (adalimumab)

Humira is an immunomodulator indicated for the treatment of several disorders. Prior authorization criteria were last revised in October 2017. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

6. Mavyret™ (glecaprevir/pibrentasvir)

Mavyret is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria was initially approved in October 2017. The prior authorization criteria are being revised to be consistent with other agents, include criteria for treatment of refractory hepatitis C, and ensure appropriate and cost-effective use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

7. Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)

Vosevi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria was last reviewed in October 2017. The prior authorization criteria are being revised to be consistent with other agents, include criteria for treatment of refractory hepatitis C, and ensure appropriate and cost-effective use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

8. Nuedexta® (dextromethorphan/quinidine)

Nuedexta is a combination product for the treatment of pseudobulbar affect (PBA). Dextromethorphan stimulates sigma-1 receptors and inhibits NMDA receptors, and quinidine inhibits dextromethorphan metabolism increasing bioavailability. The criteria was last revised in October 2011. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

9. **Opioids**

This criteria covers all short and long-acting opioids. The criteria was initially approved in January 2018. Since that time, a new short-acting opioid product containing benzhydrocodone has been FDA-approved for treatment of pain. The prior authorization criteria are being revised to include the new agent, ensure appropriate use based upon the FDA-approved labeling information, CDC guidelines, CMS Best Practices, and input from an internal team composed of members from DXC, KDHE, KDADS, and the MCOs, and to be consistent with similar agents.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

10. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations

The SGLT2 inhibitor combinations prior authorization criteria was last revised in January 2018. This revision had a typographical error during approval which has since been corrected. Also since that time, the FDA has approved two new SGLT2 inhibitor products, Steglujan and Segluromet. The criteria is being revised to correct the error, include the new products, have consistent wording for required previous medication trials, and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

11. Topical Acne Medications

Prior authorization criteria for Topical Acne Medications were last revised in January 2016. The prior authorization criteria is being revised to remove criteria for Finacea for rosacea as more current criteria for this product is included in the rosacea prior authorization criteria.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

12. Verzenio™ (abemaciclib)

Verzenio is a cyclin-dependent kinase (CDK) inhibitor, indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression following endocrine therapy. Prior authorization criteria was initially approved in January 2018. Since that time, Verzenio has been FDA-approved for use as initial endocrine based therapy, in combination with an aromatase inhibitor, for HR positive HER2 negative advanced or metastatic breast cancer in postmenopausal women. The criteria is being revised to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

13. Xgeva® (denosumab)

Xgeva is approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors, and the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Prior authorization criteria were first approved in October 2013. Since that time, Xgeva has become indicated for the use in the treatment of hypercalcemia of malignancy and multiple myeloma. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

D. New Prior Authorization (PA) Criteria

1. Anti-emetics - Cannabinoids

This criteria will combine and supersede all previous criteria for past cannabinoid agents including dronabinol agents and Cesamet. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

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2. Anti-emetics - NK-1 antagonists and NK1 combinations

This criteria will combine and supersede all previous criteria for past NK-1 antagonists and NK1 combination products. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Glucagon-Like Peptide (GLP-1) Receptor Agonists

GLP-1 receptor agonists are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. This criteria will combine and supersede all previous criteria for past PAs for all GLP-1 receptor agonists. The prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information, consolidate criteria, and to be consistent with similar agents.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Luxturna® (voretigene neparvovec-rzyl)

Luxturna is an adeno-associated virus vector-based gene therapy, indicated for the treatment of retinal dystrophy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

5. Yescarta® (axicabtagene ciloleucel)

Yescarta is a T cell immunotherapy, indicated for the treatment of relapsed or refractory large B-cell lymphoma. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

6. Proton Pump Inhibitor (PPI)

PPIs are indicated for the treatment of multiple GI disorders related to ulceration and acid production. Prior authorization criteria is being introduced to ensure appropriate use based upon the FDA-approved labeling information and include step-therapy requirements to ensure appropriate and cost-effective use.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

E. Mental Health Medication Advisory Committee (MHMAC)

1. Adult Antipsychotic Dosing Limits

At the February 2018 MHMAC meeting, the criteria was amended for a title change from "16 and Older Antipsychotic Dosing Limits" to "18 and Older Antipsychotic Dosing Limits". The revised criteria also have added medications included in this criteria and an initial written peer-to-peer consultation option.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. ORAL Benzodiazepine Dosing Limits for ≥18 Years of Age

At the February 2018 MHMAC meeting, committee approved dosing limitation criteria for use of oral benzodiazepines in patients over 18 years of age. These patients receiving an oral benzodiazepine at a dose greater than that listed in the criteria will require prior authorization that ensures safe and appropriate use.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion
- **IV. OPEN PUBLIC COMMENT**
- V. ADJOURN

ACRONYMS: CDC = CENTER FOR DISEASE CONTROL, CMS = CENTERS FOR MEDICAID AND MEDICARE, KDHE = KANSAS DEPT. OF HEALTH AND ENVIRONMENT, KDADS = KANSAS DEPARTMENT FOR AGING AND DISABILITY SERVICES, MCO = MANAGED CARE ORGANIZATION

Lunch will be provided for the DUR Board members.

The next DUR Board meeting is scheduled for July 11, 2018.

^{*}Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.